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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,862	11/20/2003	George R. Dodge	06510029US	5643

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08/09/2005

McGuire Woods LLP
Suite 1800
1750 Tysons Blvd.
McLean, VA 22102

EXAMINER

REIDEL, JESSICA L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/716,862	Applicant(s) DODGE ET AL.	
	Examiner Jessica L. Reidel	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-14, 17, 18, 20, 21 and 23-26 is/are rejected.
- 7) ☐ Claim(s) 8, 9, 15, 16, 19 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are informal. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (U.S. 6,120,502). Michelson discloses a device 10 used for reducing the growth of a bone (see Michelson column 1, lines 65-67). The device 10 comprises a power source 60 for generating current (see Michelson Abstract and Fig. 4) that is effective to reduce the growth of a bone (see Michelson column 19, lines 54-57) and at least one anode 96 of electrode 30 in electrical communication with the power source 60 (see Michelson column 9, lines 17-18 and column 10, lines 23-31). Michelson further discloses that the anode 96 of electrode 30 is adapted to apply

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the current to a predetermined location of the bone (see Michelson Fig. 3A, column 10, lines 50-52).

4. In addition to the arguments presented for the rejection of Claim 1, Claim 3 is rejected. Michelson further discloses an alternative embodiment of device 10 comprising at least one electrode 230 comprising an electrically conductive threaded portion 200 (see Michelson column 12, lines 25-34).

5. In addition to the arguments presented for the rejection of Claim 1, Claim 4 is rejected. Michelson discloses a device 10 further comprising a controller 70 in electrical communication with the power source 60 (see Michelson column 9, lines 45-46) and the at least one electrode 30 (see Michelson column 9, lines 15-24). The controller 70 distributes a predetermined current to the at least one electrode 30 (see Michelson column 9, lines 25-27).

6. In addition to the arguments presented for the rejections of Claim 1 and Claim 4, Claim 5 is rejected. Michelson discloses a device 10 further comprising a controller 70 that regulates the frequency and duration the current is distributed to the at least one electrode 30 (see Michelson column 9, lines 30-35).

7. In addition to the arguments presented for the rejections of Claim 1 and Claim 4, Claim 6 is rejected. Michelson discloses a device 10 further comprising a controller 70 that regulates the amount of the current applied to each of the at least one electrode 30 (see Michelson column 9, lines 25-27).

8. In addition to the arguments presented for the rejections of Claim 1 and Claim 4, Claim 7 is rejected. Michelson discloses a device 10 further comprising a controller 70 that regulates the amount of the current applied to each of the at least one electrode 30 (see Michelson column 9,

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lines 25-27) and the frequency and duration the current is distributed to the at least one electrode 30 (see Michelson column 9, lines 30-35).

9. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (U.S. 6,120,502). Michelson discloses a method for correcting the curvature of the spine comprising the steps of positioning at least one electrode 30 at a portion of a vertebrae near the outside curve of the spine and applying bone growth reducing current to the portion of the vertebrae where the current is effective to reduce the growth of the vertebrae at the outside of the curve (second portion) without reducing growth of the vertebrae near the inside of the curve (first portion) (see Michelson column 19, lines 54-57, column 10, lines 23-31, and Fig. 2).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. 6,120,502). Michelson discloses the claimed invention except that the device does not comprise more than one electrode in electrical communication with the power source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device comprise more than one electrode in electrical communication with the power source, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

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12. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. 6,120,502). Michelson discloses a method for reducing the growth of a bone comprising applying bone growth reducing electrical current to at least a portion of the vertebrae. The current applied is effective to reduce the growth of the bone in the applied region (see Michelson column 19, lines 54-57). Claim 10 differs from Michelson in that the current is not specifically applied to a portion of the growth plate of a bone but rather the bone growth reducing current is applied to a portion of the vertebrae. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a method step in which bone growth reducing electrical current is applied to at least a portion of a growth plate of a bone in order to reduce growth of the bone at the growth plate, since it has been held that rearranging parts of an invention involves only routine skill in the art.

13. In addition to the arguments presented for the rejection of Claim 10, Claim 11 is rejected. Michelson further discloses a method where the bone growth reducing electrical current is effective to arrest the growth of the bone in the applied region (see Michelson column 19, lines 54-57 and column 3, lines 5-7).

14. In addition to the arguments presented for the rejection of Claim 10, Claim 12 is rejected. Michelson further discloses a method where the bone growth reducing electrical current is effective to arrest the growth of the entire bone by "inhibiting bone formation" (see Michelson column 1, lines 65-67).

15. In addition to the arguments presented for the rejection of Claim 10, Claim 13 is rejected. Michelson further discloses a method comprising positioning at least one electrode 30 near the

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bone and applying the bone growth reducing electrical current to the adjacent bone through the at least one electrode 30 (see Michelson column 19, lines 44-46 and lines 54-57).

16. In addition to the arguments presented for the rejection of Claim 10, Claim 14 is rejected. Michelson further discloses a method comprising positioning at least one electrode 30 near the bone and applying the bone growth reducing electrical current to the adjacent bone through the at least one electrode 30 (see Michelson column 19, lines 44-46 and lines 54-57). Michelson further discloses a method providing a controller 70 in electrical communication with a power source 60 (see Michelson column 9, lines 45-46) and at least one electrode 30 (see Michelson column 9, lines 15-24). The controller 70 distributes a predetermined current to the at least one electrode 30 (see Michelson column 9, lines 25-27). Michelson discloses the claimed method except for monitoring the change in growth of the bone. It is inherent, or at least obvious to one having ordinary skill in the art at the time the invention was made, to monitor the change in growth of the bone, as monitoring electrical stimulation of a patient is common knowledge in the art.

17. In addition to the arguments presented for the rejections of Claim 10 and Claim 13, Claim 17 is rejected. Michelson discloses a method for reducing the growth of a bone comprising applying bone growth reducing electrical current to at least a portion of the vertebrae where the electrode is positioned in the vertebrae. The current applied is effective to reduce the growth of the bone in the applied region (see Michelson column 19, lines 54-57). Michelson differs from Claim 17 in that the electrode is not positioned in the growth plate of a bone, but positioned in-between two vertebrae. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a method step in which the electrode is positioned in the

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growth plate of a bone in order to reduce growth of the bone at the growth plate, since it has been held that rearranging parts of an invention involves only routine skill in the art.

18. In addition to the arguments presented for the rejection of Claim 18, Claim 20 is rejected. Michelson further discloses a method comprising positioning an electrode between two vertebrae where the second portion of the electrode stimulates the outside curve of the spine (see Michelson column 19, lines 54-57 and Fig. 2). Michelson also discloses providing a power source 60 in electrical communication with the electrode 30 that generates the bone growth reducing current (see Michelson column 9, lines 17-18 and column 10, lines 23-31) and a controller 70 that regulates the amount of the current applied to the electrode (see Michelson column 9, lines 25-27). Claim 20 differs from Michelson in that the method does not comprise more than one electrode in electrical communication with the power source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device comprise more than one electrode in electrical communication with the power source, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

19. In addition to the arguments presented for the rejections of Claim 18 and Claim 20, Claim 21 is rejected. Michelson discloses a method further comprising a controller 70 that regulates the frequency and duration the current is distributed to the electrode 30 via a pulse generator (see Michelson column 9, lines 30-35). It is well known in the art that pulse generators are devices that produce an electrical discharge at regular intervals, which can be modified as needed regarding frequency and duration the charge is distributed.

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20. In addition to the arguments presented for the rejections of Claim 18 and Claim 20, Claim 23 is rejected. Michelson discloses a method further comprising a controller 70 that regulates the amount, frequency, and duration the current is distributed to the electrode 30 (see Michelson column 9, lines 25-27 and lines 30-35). It is inherent, or at least obvious to one of ordinary skill in the art that the time of the invention that the controller 70 must be programmed to accomplish these tasks.

21. In addition to the arguments presented for the rejection of Claim 18, Claim 24 is rejected. Michelson discloses a method further comprising providing an electrode on a portion of the vertebrae along the inside of the curve of the spine (first positively charged portion of the electrode, right side of Fig. 2) and applying a bone growth stimulating current to the electrode (see Michelson column 19, lines 41-53 and Fig. 2). Claim 24 differs from Michelson in that the method does not comprise a second electrode in electrical communication with the power source applying bone growth stimulating current to the inside portion of the vertebrae. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the device comprise more than one electrode in electrical communication with the power source, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

22. In addition to the arguments presented for the rejection of Claim 18, Claim 25 is rejected. Michelson discloses a method for reducing the growth of a bone comprising applying bone growth reducing electrical current to at least a portion of the vertebrae where the electrode is positioned in the vertebrae. The current applied is effective to reduce the growth of the bone in the applied region (see Michelson column 19, lines 54-57). Michelson differs from Claim 25 in

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that the electrode is not positioned in the growth plate of a bone, but positioned in-between two vertebrae. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a method step in which the electrode is positioned in the growth plate of a bone in order to reduce growth of the bone at the growth plate, since it has been held that rearranging parts of an invention involves only routine skill in the art.

23. In addition to the arguments presented for the rejection of Claim 18, Claim 26 is rejected. Michelson discloses a method for reducing the growth of a bone comprising applying bone growth reducing electrical current to at least a portion of the vertebrae where the electrode is positioned in the vertebrae. The current applied is effective to reduce the growth of the bone in the applied region (see Michelson column 19, lines 54-57). Michelson differs from Claim 26 in that the electrode is not positioned near a growth plate of a bone, but positioned in-between two vertebrae. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a method step in which the electrode is positioned near a growth plate of a bone in order to reduce growth of the bone at the growth plate, since it has been held that rearranging parts of an invention involves only routine skill in the art.

Allowable Subject Matter

24. Claims 8-9, 15-16, 19 and 22 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Liboff et al. (U.S. 5,458,558) discloses a method and apparatus for controlling bone growth (promoting and inhibiting) with an applied fluctuating magnetic field. Soltis et al. (U.S. 6,704,605) discloses a threaded electrode for tissue stimulation that provides superior mechanical fixation and electrical stimulation of tissue such as bone. Michelson (U.S. 6,605,089), a continuation of Michelson (U.S. 6,120,502) discloses a method and apparatus for controlling bone growth (promoting and inhibiting) that allows for variation in application of the bone growth reducing current by varying the area of the screw head 121, as shown in FIG. 4 of U.S. 6,605,089, where the area of screw head 121 has been deliberately increased to inhibit bone formation in an area adjacent to the screw head 121.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3762

Jessica L. Reidel 